K020200

9. 510(k) SUMMARY MAR 1 3 2002

A. SUMMARY OF SAFETY AND EFFECTIVENESS

1. COMPANY NAME - Playtex Products Inc.

ADDRESS - 75 Commerce Drive
Allendale, New Jersey 07401

TELEPHONE - 201-785-8000

CONTACT PERSON - M. Rosengarten
Director, Regulatory, Safety & International Development

DATE OF SUMMARY - January 18, 2002

2. DEVICE NAME - Playtex Tampons

CLASSIFICATION NAME - Scented, Deodorized Menstrual Tampons

3. The new Playtex tampons are substantially equivalent to the following tampons that have been previously cleared:
   a. Playtex Deodorant Gentle Glide® in Regular, Super and Super Plus absorbencies
   b. Playtex Deodorant Portables® in Regular and Super absorbencies
   c. Playtex Deodorant Gentle Glide Multipack in Regular and Super absorbencies
   d. Deodorant Slimfits® in Regular absorbency

4. The device description is: Scented, deodorized menstrual tampons for the absorption of menstrual fluid.

5. Playtex tampons are intended to be used as scented, deodorized menstrual tampons for the absorption of menstrual fluid.

6. The new tampon has the same technological characteristics as the predicate device. The fiber, string and materials in contact with the vaginal wall are the same or have the same mode of action.

B. 1. Nonclinical testing referenced for the determination of substantial equivalence includes:

Human sensitization, dermal irritation, acute oral toxicity, subacute vaginal irritations, agar diffusion and TSST-1 toxin testing.

2. Based on the review of the data referenced in this "510(k) Summary," the Playtex tampons are substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2002

Mr. Mark E. Rosengarten
Director, Regulatory, Safety &
International Development
Playtex Products, Inc.
Technical Center
75 Commerce Dr.
ALLENDALE NJ 07401-1600

Re: K020200
Trade/Device Name: Playtex Deodorant Tampons
Model 34802
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or scented deodorized
menstrual tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HIL and HEB
Dated: January 18, 2002
Received: January 22, 2002

Dear Mr. Rosengarten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS OF USE PAGE

510(k) Number (if known): K020200

Device Name: Playtex Deodorant Gentle Glide®, Playtex Deodorant Portables®, Playtex Deodorant Gentle Glide® Multipack and Playtex Deodorant Slimfits® Tampons Model #34802

Indications For Use:

Scented or scented, deodorized menstrual tampon for the absorption of menstrual fluid.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020200